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Bearing structure

The invention concerns a one-piece expandable flat bearing structure. That bearing structure is formed by at least partially elastically deformable struts which are separated from each other by openings in the bearing structure. The bearing structure can assume at least one compressed condition and at least one expanded condition and has at least one expansion direction into which the bearing structure can expand from the compressed condition to the expanded condition.

The invention concerns in particular endoluminal prostheses and in particular stents with such a bearing structure.

The term flat bearing structure is here also used to denote such a bearing structure which forms for example the peripheral wall of a tubular article which is open at its two ends. Such a tubular article which is open at both ends is represented by per se known stents.

Stents are used in many cases as implantable vessel supports. Known stents are urethra stents as well as coronary stents and peripheral stents. Coronary stents serve to deal with vessel constrictions in the

coronary blood vessels, so-called stenoses, by means of a radial supporting action which emanates from the stent. The same is implemented by peripheral stents for peripheral blood vessels.

Many stents of that kind are produced from a one-piece tube as the starting material by cutting for example by means of a laser. The cuts into the tube serving as the starting material provide a bearing structure of struts and openings which are disposed therein, which structure can be radially expanded in the case of stents. In particular the expanded bearing structure is grid-like and has struts which enclose radial openings of greater or lesser size in the stent. Balloon-expandable stents and self-expandable stents are known. Self-expandable stents comprise for example a memory metal such as nitinol which, upon reaching a jump temperature, jumps from a first shape corresponding to the compressed condition of the stent to a second shape corresponding to the expanded condition of the stent.

The balloon-expandable stents which are of particular interest in the present context do not automatically change from the compressed to the expanded condition but rather are expanded by means of a balloon which is pumped up with a fluid in the interior of the stents. A balloon of that kind is generally arranged at the end of a balloon catheter which serves at the same time for introducing the stent as far as the location to be treated at the vessel constriction. For that purpose the stent is crimped onto the balloon. The stent is expanded by means of the balloon at the treatment location.

The demands made on stents of that kind are many and various. In order on the one hand to be well introduced into a blood vessel and on the other hand to sufficiently expand a stenosis, the bearing structure of the stent must be capable of being expanded from a compressed diameter which is as small as possible to a sufficiently large expanded diameter. The expanded bearing structure must also enjoy a sufficient radially acting bearing force, also referred to as radial strength, in order to reliably hold the vessel open. Further desirable properties are suitable surface

coverage by the expanded stent as well as appropriate behavior upon flexing about the longitudinal axis of the stent as is frequently required in relation to blood vessels in the human body. A further demand on bearing structures for stents is that a balloon-expandable stent is to spring back again as little as possible after expansion by the balloon. More specifically, the consequence of such spring-back effect on the part of the bearing structure after expansion by a certain amount is that the bearing structure has to be expanded by that amount beyond the desired final dimension so that ultimately the bearing structure assumes the desired final stent dimension. That spring-back effect on the part of the bearing structure immediately after expansion when the balloon serving for expansion is deflated again is referred to as recoil.

The co-operation of material property and stent design lead to the structural properties of the stent. To assess a stent design and for comparison with other stents, reference is made to characteristic values which are set forth in the following section. In order to obviate misunderstandings it should be noted at this juncture that this involves pure engineering characteristic values for describing the stent properties, which are not to be confused with the situation in the vessel.

Recoil:

Recoil describes the elastic spring-back effect during or after evacuation of the balloon catheter. It is defined as the relative difference between the diameter at maximum pressure and the diameter after balloon evacuation.

Radial strength:

Radial strength specifies the maximum external pressure that the stent withstands. The characteristic value is the collapse pressure which is defined as the pressure at which the stent has collapsed.

Shortening:

The stent can shorten during stent dilation. The parameter describing that phenomenon is called shortening and is defined as the

relative difference between the length prior to dilation and the final length.

Flexural stiffness:

The coronary vessels generally do not extend in a straight line but twisted so that the stent should be as flexurally soft as possible for easy passage to the implantation location. In addition flexurally soft stent designs permit stent implantation in curved and branched coronary vessels [4]. The flexural stiffness of stents is ascertained as structural stiffness EI with the unit [Nmm] from a flexural test [5].

Further parameters:

The expansion behavior, crimpability and compliance are further considered.

Expansion behavior is determined by the balloon pressure at which the stent opens, free deployment of the struts takes place and so forth. Crimpability influences handling of the stent from the point of view of the cardiologist or machine crimping in the case of the complete systems.

It is very difficult to arrive at a relationship between the mechanical characteristic values of a stent and its biocompatibility and specifically hemocompatibility. Biocompatibility is composed of surface compatibility and structural compatibility. In the case of a stent surface compatibility involves blood contact on the one hand and tissue contact with the vessel wall on the other hand. Structural compatibility extends from the mechanical supporting effect by way of flexural stiffness and the strut shape to the fluidic influences on the blood flow. The stent should not destroy the vessel, it should not result either in mechanical or toxic irritations and it should be athrombogenic in terms of blood contact.

The man skilled in the art is aware of a large number of bearing structures for stents, which all afford various advantages and conversely frequently also entail certain disadvantages. The known bearing structures for example can frequently be embodied only insufficiently or not at all with the materials which have a low modulus of elasticity. Most of the known bearing structures presuppose materials which can be well

plastically deformed. That is important in particular in regard to the above-indicated requirement for keeping recoil as low as possible.

With that background in mind the object of the present invention is to provide a bearing structure which satisfy the manifold demands on a bearing structure for a stent and which can also be implemented with materials of a low modulus of elasticity.

In accordance with the invention that object is achieved by a bearing structure of the kind set forth in the opening part of this specification, which has anchor regions from which spring struts which elastically return with respect to the anchor regions extend to a resiliently deflectable end of the spring struts. A hinge strut adjoins the resiliently deflectable end of the spring struts. The spring struts and the hinge struts are of such a configuration and arrangement that the spring struts are firstly resiliently deflected transversely with respect to the expansion direction during the transition from the compressed condition to the expanded condition of the bearing structure by the folding-over hinge struts and finally recoil. At the same time a respective central axis of the hinge struts is pivoted away about a hinge axis extending transversely with respect to the bearing structure beyond a reference axis which extends within the bearing structure transversely with respect to the expansion direction and transversely with respect to the hinge axis. The configuration and arrangement of spring struts and hinge struts is such that both the compressed condition of the bearing structure and also the expanded condition is stabilized by a spring action emanating from the spring struts.

The invention is based on the idea that materials of a low modulus of elasticity resiliently yield more easily to deformation forces, instead of plastically deforming. In that respect elastic deformation of the bearing structure usually results in unwanted recoil.

Unlike all known bearing structures the bearing structure which is described herein makes it possible to use the spring forces linked to the elastic deformation of the bearing structure for stabilization of the bearing

structure both in the compressed condition and also and in particular in the expanded condition. The bearing structure described herein snaps virtually upon expansion into the expanded condition. The supporting effect of the bearing structure is not impaired somewhat by the spring forces but on the contrary is even further enhanced.

Hinge struts and spring struts in this bearing structure are of such a configuration and arrangement relative to each other that, by virtue of the spring action emanating from the spring struts, the spring struts apply to the hinge struts a moment which rotates the hinge struts after expansion of the bearing structure beyond a certain amount in the direction corresponding to the position of the hinge struts in the expanded condition.

Preferably the two longitudinal ends of a respective hinge strut are respectively engaged by a spring strut which jointly rotate the hinge strut in the same direction about the hinge axis, that is to say they apply a moment in the same direction to the hinge strut. For that purpose the two spring struts adjoining a respective hinge strut are preferably shaped and arranged in point-symmetrical relationship with each other.

The bearing structure involved here is basically suitable for many different uses. A particularly preferred use is one in which the bearing structure forms a peripheral wall of a stent. The subject of the present application is thus also a stent with a bearing structure as described here.

In this respect the bearing structure of the stent is preferably so arranged that the expansion direction extends in the peripheral direction of the stent so that the reference axis beyond which the hinge struts are pivoted extends in parallel relationship with or at a shallow angle to the longitudinal direction of the stent while the hinge axis about which the hinge struts are hinged is oriented approximately radially with respect to the stent. Such an arrangement of the bearing structure imparts a high level of radial strength in the expanded condition even to a stent comprising a material with a low modulus of elasticity.

A bearing structure of that kind can be formed in particular also from plastic material or a magnesium alloy. By virtue of their low modulus of elasticity those materials usually entailed major disadvantages when used as a material for stents. The subject-matter of this application is thus also stents which are of a bearing structure as described here and whose material is plastic material, in particular polymers or a magnesium alloy.

A particularly preferred stent is a stent comprising biodegradable material, in particular a magnesium alloy or a polymer such as poly-β-hydroxybutyric acid (PHB), poly-ε-caprolacton (PCL) and poly-L-lactide (PLLA). A suitable polymer blend comprises 80% PLLA, 10% PCL and 10% triethylcitrate (TEC).

The above-described bearing structure preferably has openings which are cut so that the struts are separated from each other by cuts. Such cuts can be produced for example by means of a laser. In that case, a suitable starting material for a bearing structure for a stent is a tube portion comprising the stent material, which is subjected to further processing by laser cutting to afford the bearing structure.

The shape of the hinge struts which are separated by the cuts from the adjacent bearing structure, in particular from the spring struts, is preferably S-shaped or W-shaped in the compressed condition of the bearing structure.

Preferably the cuts have end regions which are enlarged to avoid a notch effect and in particular to reduce edge fiber stretching in the end region of the cuts. Alternative solutions for reducing edge fiber stretching in the end region of the cuts are set forth the context of the specific description hereinafter and illustrated in the drawing.

The spring struts are preferably so shaped that in the proximity of the anchor regions they involve a larger cross-sectional area than in the region of their resiliently deflectable ends. In particular it has proven to be advantageous if the spring struts steadily narrow starting from the anchor regions towards the resiliently deflectable ends. The hinge struts

on the other hand are of a substantially uniform cross-section in transverse relationship with their central axis. It is particularly preferred if a transitional region of a cross-section which is reduced with respect to the hinge strut is provided between a respective resiliently deflectable end of a spring strut and the hinge strut adjoining same.

The invention will now be described in greater detail by means of embodiments by way of example with reference to the accompanying drawings in which:

Figure 1a shows a development of the peripheral wall of a first variant of a coronary stent.

Figure 1b shows a three-dimensional model of a portion of the first variant of a coronary stent with a bearing structure corresponding to the development in Figure 1a,

Figure 2 shows three views which serve to explain the mode of operation of the bearing structure and which from left to right correspond to a compressed condition, a transitional condition and an expanded condition,

Figure 3 shows six variants in regard to the configuration of the end region of the cuts for the bearing structure of Figure 1,

Figure 4a shows a development of a bearing structure for a second variant of a coronary stent,

Figure 4b shows a 3D-model of a portion of the second variant of a stent corresponding to the development of Figure 4a,

Figure 5a shows a development of a bearing structure for a third variant of a coronary stent,

Figure 5b shows a 3D-model of a stent portion in accordance with the third variant with the development of Figure 5a,

Figure 6a shows a development of a bearing structure for a fourth variant of a coronary stent,

Figure 6b shows a 3D-model of a portion of the fourth variant of a stent corresponding to the development of Figure 6a,

Figure 7a shows a development of a bearing structure for a fifth variant of the coronary stent,

Figure 7b shows a 3D-model of a portion of the fifth variant of the coronary stent corresponding to the development from Figure 7a,

Figure 8 shows a side view of a stent portion corresponding to the fifth variant in Figures 7a and b,

Figure 9 shows a photograph of the variant of Figures 7a through 8, showing the compressed condition of the fifth variant,

Figure 10 shows a photograph of the fifth variant of Figure 9 in the expanded condition,

Figure 11a shows the development of a bearing structure for a first variant of urethra stent,

Figure 11b shows a 3D-model of the first variant for a urethra stent with a development as shown in Figure 11a,

Figure 12a shows the development of a bearing structure for a second variant of a urethra stent,

Figure 12b shows a 3D-model of the second variant for a urethra stent with a development as shown in Figure 12a,

Figure 13a shows a 3D-model of the second variant of Figures 12a and 12b showing both the compressed condition of that variant and also the balloon-expanded condition of the variant, and

Figure 13b shows the second variant of the urethra stent after elastic recoil.

The development of a bearing structure 10 for a first variant of a coronary stent has spring struts 12 which respectively start from an anchor region 14 and enclose in pairs between them a respective hinge strut 16.

The development in Figure 1a corresponds to a coronary stent of which a longitudinal portion 20 is shown in Figure 1b in the form of a 3D-model. Spring struts 12 and hinge struts 16 are separated from each other by cuts 18 forming openings. The cuts 18 are all of a W-shape in the embodiment of Figure 1a.

All coronary stents illustrated in Figures 1 through 10 are preferably made from bioresorbable material, in particular a polymer poly-β-hydroxybutyric acid (PHB), poly-ε-caprolacton (PCL) and poly-L-lactide (PLLA). A polymer blend of 80% PLLA, 10% PCL and 10% triethylcitrate (TEC) is also highly suitable.

The dimensions of the coronary stents of Figures 1 through 10 in the expanded condition are as follows: diameters between 2 and 6 mm and lengths between 6 and 40 mm. On average those coronary stents involve diameters of 3.5 and 4 mm and lengths of about 20 mm.

Figure 2 shows the co-operation of the essential structural elements of a bearing structure in three conditions, namely at the left in the compressed condition of the bearing structure, in the center in a transitional condition from the compressed to the expanded condition of the bearing structure and at the right in the expanded condition of the bearing structure. A hinge strut 30 extends from an anchor region 32 to an elastically resilient end 34. A hinge strut 36 adjoins the resiliently deflectable end 34 of the spring strut 30. An expansion direction x is shown at the right in Figure 2.

In the compressed condition of the bearing structure as shown on the left the hinge strut 36 bears closely against the spring strut 30. The spring strut 30 and the hinge strut 36 are separated from each other by a cut 38. The longitudinal axis of a stent corresponding to the view extends in parallel relationship with a horizontal line in the plane of the illustration in Figure 2. Radial expansion of such a stent corresponds to expansion of the bearing structure in the direction indicated by x in Figure 2.

The consequence of expansion of the structure in Figure 2 is that the hinge strut 36 is pivoted in the direction indicated by x. In that way the spring strut 30 is resiliently deflected in the direction shown by the wide arrow in the middle view in Figure 2. At the same time the spring strut 30 applies to the hinge strut 36 a moment which acts in opposite relationship to the direction of the arrow. In the middle view in Figure 2 a center line of the hinge strut 36 extends approximately in the direction of

a reference line which extends in parallel relationship with the longitudinal axis of the stent and at the same time in parallel relationship with a horizontal line in the plane of the view in Figure 2.

The right view in Figure 2 corresponds to the expanded condition of a bearing structure. The center line of the hinge strut 36 is pivoted beyond the reference line – that is to say beyond the condition illustrated in the central view – with the consequence that the spring strut 30 can recoil in the direction shown by the broad arrow in the right view in Figure 2. Accordingly, in the expanded condition of the bearing structure, the spring action emanating from the spring strut 30 promotes the orientation of the hinge strut 36. In that way the expanded condition of the bearing structure is stabilized by the spring action emanating from the spring strut 30. That enhances the radial strength of an expanded stent with a bearing structure as described herein.

It can already be seen from Figure 1a that the spring struts 12 are arranged in pairs and enclose a respective hinge strut between them. That serves for further enhancing radial strength. This arrangement of the struts, which is selected for all variants illustrated in Figures 1 through 13, affords the possibility of markedly configuring a kind of pair of spring struts which, after expansion, acts jointly on a hinge strut and thus prevents or reduces the recoil effect.

Due to the expansion action the left spring strut of a pair of spring struts is urged towards the left and stores energy as a kind of leaf spring.

The right-hand spring strut of the same pair of spring struts is urged towards the right and also stores energy. As soon as the spring struts have slid past each other or the hinge strut is pivoted beyond the reference line, the spring struts return due to the stored energy, as shown in the right view in Figure 2, and prevent recoil. The spring struts are dimensioned approximately in accordance with the loadings involved, if reference is directed in respect of the loadings involved to the expansion process and not to the radial strength.

The S-shaped hinge struts adopted for the coronary stents in Figures 1 through 10 are of a small structural height so that they can be favorably distributed over the small periphery of a coronary stent. In addition S-shaped hinge struts can be easily connected to pairs of spring struts whose markedness however is not so clearly noticeable as in the case of alternatively possible spiral-shaped struts as are provided for the urethra stents shown in Figures 11 through 13. Spiral-shaped struts are of a larger structural height and therefore cannot be distributed in a sufficient number over the relatively small periphery of a coronary stent.

It can already be seen from Figure 1a that end regions of the cuts 18 are of an enlarged configuration to reduce the edge fiber stretching effect in the transitional region from a resiliently deflectable end of a spring strut 12 to the adjoining hinge strut 16. The corresponding end portions of the cuts 18 are identified by 22 in Figure 1a.

Figure 3 shows various variants of the configuration for the cuts which separate spring struts and hinge struts from each other. Figure 3 shows in particular six variants of possible configurations in respect of the bending radii at the end of a respective cut, wherein variant 1 represents as an initial shape a design with S-shaped struts. Variants 2, 3 and 6 use a kind of termination arc to increase the bending radius, while a straight termination line is added to variants 4 and 5. The configurations of the end regions of the cuts, which are shown in variants 2 through 6, provide that edge fiber stretching upon expansion of the bearing structure in the transitional region from a spring strut to a hinge strut is advantageously reduced.

The variants 3, 4 and 5 afford the least edge fiber stretching. If the recoil is to be kept as slight as possible, the variants 3 and 5 are to be preferred to the others.

The variant 5 in Figure 3 corresponds in that respect to the embodiment of Figures 1a and 1b. Besides the end of the cut being rounded off, the variant 1 shown in Figure 3 does not involve any particular features for reducing edge fiber stretching. The variants 3, 4, 5

and 6 in regard to the configuration of the end region of cuts, like the cuts 18 in Figure 1, each afford a respective transitional region between the elastically deflectable end of a spring strut and the adjoining hinge strut which is reduced in its cross-section with respect to the cross-section of the spring strut and the hinge strut. A transitional region of that kind, of reduced cross-section, has a pivot joint-like action.

The second variant of a coronary stent, as is shown in Figures 4a and 4b, differs the variant illustrated in Figures 1a and 1b only in respect of the configuration of the end regions 24 of the cuts 18. The configuration of the end portions 24 of the cuts 18 corresponds to the variant 3 in Figure 3.

The third embodiment of a coronary stent, as is illustrated in Figures 5a and 5b, embodies a design which combines S-shaped struts with angular struts. The combined design provides that the stent increases in length during expansion until the longitudinal struts "flip over". After flipping-through of the zig-zag line the stent is reduced in length again. A spring-back effect is made more difficult in that way so that the recoil is less.

Figures 6 and 7 show designs for coronary stents with enhanced radial strength. Mutual displacement of adjacent rings formed by pairs of spring struts which occur in succession in the radial direction, with hinge struts disposed therebetween, serves to increase the level of radial strength. That affords a zig-zag line in respect of stiffness. In the ideal situation, after expansion soft regions lie beside stiff regions on a line along the axis of the stent, whereby the struts only fail due to buckling under relatively high pressures.

In the design shown in Figure 6 the displacement between the struts is half an element height while in Figure 7 it is a full element height. The term element height is used here to denote the radial extent of a pair of spring struts with hinge strut disposed therebetween.

Figures 11 through 13 show urethra stents. They are of a larger diameter of about 10 mm, in comparison with coronary stents. That

makes it possible for the illustrated spiral design to be imparted to the hinge struts.

The flexural stiffness of the stent designs set forth here is based on the continuous limbs which extend over the entire stent length. It can be reduced by continuous limbs in the longitudinal direction of the stent being severed.